



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

CAI *et al.*

Appl. No.: 10/572,910

§ 371 Date: March 21, 2006

For: **Substituted 2-Arylmethylene-N-aryl-N'-aryl-malonamides and Analogs as Activators of Caspases and Inducers of Apoptosis**

Confirmation No.: 4626

Art Unit: 1614

Examiner: Weddington, Kevin E.

Atty. Docket: 1735.0930001/RWE/BSA

**Information Disclosure Statement**

***Mail Stop Amendment***

Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

Sir:

Listed on accompanying IDS Forms are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98. Copies of documents FP1 and NPL1-NPL38 are submitted. However, in accordance with 37 C.F.R. § 1.98(a)(2), no copies of U.S. patents and patent application publications cited on the attached IDS Forms are submitted.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached IDS Forms based on information presently available to the undersigned. However, the listed publication

dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

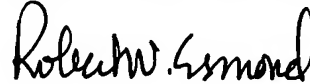
This Information Disclosure Statement is being filed within three months of the date of entry of the national stage as set forth in 37 C.F.R. § 1.491 in an international application or before the mailing date of a first Office Action on the merits. No statement or fee is required.

It is respectfully requested that the Examiner initial and return a copy of the enclosed IDS Forms, and indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

A handwritten signature in black ink, appearing to read "Robert W. Esmond". The signature is fluid and cursive, with the first name "Robert" and last name "Esmond" clearly distinguishable.

Robert W. Esmond  
Attorney for Applicants  
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Date: July 26, 2007

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<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> (Use as many sheets as necessary)				<b>Complete if Known</b>	
				Application Number	10/572,910
				§ 371 Date	March 21, 2006
				First Named Inventor	Sui Xiong CAI
				Art Unit	1614
				Examiner Name	Weddington, Kevin E.
Sheet	1	of	1	Attorney Docket Number	1735.0930001/RWE/BSA

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if Known)			
	US1	4,634,777	01-06-1987	Satoh <i>et al.</i>	
	US2	6,335,429 B1	01-01-2002	Cai <i>et al.</i>	
	US3				
	US4				
	US5				
	US6				
	US7				
	US8				
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		Country Code <sup>3</sup> Number <sup>4</sup> Kind Code <sup>5</sup> (if known)				
	FP1	WO 96/20721	07-11-1996	The General Hospital Corporation		
	FP2					
	FP3					
	FP4					
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NON PATENT LITERATURE DOCUMENTS			
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	NPL1	Adjei, A.A. <i>et al.</i> , "Synergy of the Protein Farnesyltransferase Inhibitor SCH66336 and Cisplatin in Human Cancer Cell Lines," <i>Clin. Cancer Res.</i> 7:1438-1445, American Association for Cancer Research, Inc. (2001)	
	NPL2	Almond, J.B. and Cohen, G.M., "The proteasome: a novel target for cancer chemotherapy," <i>Leukemia</i> 16:433-443, Nature Publishing Group (April 2002)	
	NPL3	Batteux, F. <i>et al.</i> , "Gene Therapy of Experimental Autoimmune Thyroiditis by In Vivo Administration of Plasmid DNA Coding for Fas Ligand," <i>J. Immunol.</i> 162:603-608, The American Association of Immunologists (1999)	
	NPL4	Blanke, C.D., "Celecoxib With Chemotherapy in Colorectal Cancer," <i>Oncology (Huntingt)</i> 16(No. 4 Suppl. 3):17-21, Karger (April 2002)	
	NPL5	Boirivant, M. <i>et al.</i> , "Lamina Propria T Cells in Crohn's Disease and Other Gastrointestinal Inflammation Show Defective CD2 Pathway-Induced Apoptosis," <i>Gastroenterology</i> 116:557-565, W.B. Saunders (1999)	
	NPL6	Chinnaiyan, A.M. <i>et al.</i> , "The inhibition of pro-apoptotic ICE-like proteases enhances HIV replication," <i>Nat. Med.</i> 3:333-337, Nature Publishing Company (1997)	
	NPL7	Coven, T.R. <i>et al.</i> , "PUVA-induced lymphocyte apoptosis: Mechanism of action in psoriasis," <i>Photodermatol. Photoimmunol. Photomed.</i> 15:22-27, Blackwell Munksgaard (1999)	
	NPL8	Crawford, K.W. and Bowen, W.D., "Sigma-2 Receptor Agonists Activate a Novel Apoptotic Pathway and Potentiate Antineoplastic Drugs in Breast Tumor Cell Lines," <i>Can. Res.</i> 62:313-322, American Association for Cancer Research, Inc. (January 2002)	
	NPL9	Ellis, R.E. <i>et al.</i> , "Mechanisms and Functions of Cell Death," <i>Ann. Rev. Cell Biol.</i> 7:663-698, Annual Reviews, Inc. (1991)	
	NPL10	Friesen, C. <i>et al.</i> , "Involvement of the CD95 (APO-1/Fas) receptor/ligand system in drug-induced apoptosis in leukemia cells," <i>Nat. Med.</i> 2:574-577, Nature Publishing Co. (1996)	

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				Art Unit	1614
				Examiner Name	Weddington, Kevin E.
Sheet	2	of	4	Attorney Docket Number	1735.0930001/RWE/BSA

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume number, publisher, city and/or country where published	T <sup>2</sup>
	NPL11	Giermasz, A. <i>et al.</i> , "Potentiating Antitumor Effects of a Combination Therapy with Lovastatin and Butyrate in the Lewis Lung Carcinoma Model in Mice," <i>Int. J. Cancer</i> 97:746-750, Wiley-Liss, Inc. (February 2002)	
	NPL12	Heenen, M. <i>et al.</i> , "Methotrexate induces apoptotic cell death in human keratinocytes," <i>Arch. Dermatol. Res.</i> 290:240-245, Springer-Verlag (1998)	
	NPL13	Infante, A.J. <i>et al.</i> , "The clinical spectrum in a large kindred with autoimmune lymphoproliferative syndrome caused by a Fas mutation that impairs lymphocyte apoptosis," <i>J. Pediatr.</i> 133:629-633, Mosby, Inc. (1998)	
	NPL14	Kalemkerian, G.P. and Ou, X., "Activity of fenretinide plus chemotherapeutic agents in small-cell lung cancer cell lines," <i>Cancer Chemother. Pharmacol.</i> 43:145-150, Springer-Verlag (1999)	
	NPL15	Kelland, L.R. <i>et al.</i> , "Preclinical Antitumor Activity and Pharmacodynamic Studies with the Farnesyl Protein Transferase Inhibitor R115777 in Human Breast Cancer," <i>Clin. Cancer Res.</i> 7:3544-3550, American Association for Cancer Research, Inc. (2001)	
	NPL16	Kyprianou, N. and Benning, C.M., "Suppression of Human Prostate Cancer Cell Growth By $\alpha$ 1-Adrenoceptor Antagonists Doxazosin and Terazosin via Induction of Apoptosis," <i>Cancer Res.</i> 60:4550-4555, American Association for Cancer Research, Inc. (2000)	
	NPL17	Liu, W.M. <i>et al.</i> , "The <i>in vitro</i> activity of the tyrosine kinase inhibitor ST1571 in BCR-ABL positive chronic myeloid leukaemia cells: synergistic interactions with anti-leukaemic agents," <i>Br. J. Cancer</i> 86:1472-1478, Nature Publishing Group (May 2002)	
	NPL18	López-Hoyos, M. <i>et al.</i> , "Regulation of B cell apoptosis by Bcl-2 and Bcl-X <sub>L</sub> and its role in the development of autoimmune diseases (Review)," <i>Int. J. Mol. Med.</i> 1:475-483, D. A. Spandidos (1998)	
	NPL19	Los, M. <i>et al.</i> , "Cross-Resistance of CD95- and Drug-Induced Apoptosis as a Consequence of Deficient Activation of Caspases (ICE/Ced-3 Proteases)," <i>Blood</i> 90:3118-3129, The American Society of Hematology (1997)	
	NPL20	Motwani, M. <i>et al.</i> , "Augmentation of Apoptosis and Tumor Regression by Flavopiridol in the Presence of CPT-11 in Hct116 Colon Cancer Monolayers and Xenografts," <i>Clin. Cancer Res.</i> 7:4209-4219, American Association for Cancer Research, Inc. (2001)	

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	NPL21	Ohsako, S. and Elkon, K.B., "Apoptosis in the effector phase of autoimmune diabetes, multiple sclerosis and thyroiditis," <i>Cell Death Differ.</i> 6:13-21, Nature Publishing Group (1999)		
	NPL22	O'Reilly, L.A. & Strasser, A., "Review: Apoptosis and autoimmune disease," <i>Inflamm. Res.</i> 48:5-21, Birkhäuser Verlag, Basel (1999)		
	NPL23	Orrenius, S., "Apoptosis: molecular mechanisms and implications for human disease," <i>J. Internal Med.</i> 237:529-536, Blackwell Science Ltd. (1995)		
	NPL24	Ozawa, M. <i>et al.</i> , "312-nanometer Ultraviolet B Light (Narrow-Band UVB) Induces Apoptosis of T Cells within Psoriatic Lesions," <i>J. Exp. Med.</i> 189:711-718, The Rockefeller University Press (1999)		
	NPL25	Regar, E. <i>et al.</i> , "Stent development and local drug delivery," <i>Br. Med. Bull.</i> 59:227-248, Oxford University Press (2001)		
	NPL26	Savill, J., "Apoptosis in resolution of inflammation," <i>J. Leukoc. Biol.</i> 61:375-380, Wiley-Liss (1997)		
	NPL27	Schmitt, E. <i>et al.</i> , "The Bcl-xL and Bax-α control points: modulation of apoptosis induced by cancer chemotherapy and relation to TPCK-sensitive protease and caspase activation," <i>Biochem. Cell Biol.</i> 75:301-314, National Research Council of Canada (1997)		
	NPL28	Sgadari, C. <i>et al.</i> , "HIV protease inhibitors are potent anti-angiogenic molecules and promote regression of Kaposi sarcoma," <i>Nat. Med.</i> 8:225-232, Nature America Inc. (March 2002)		
	NPL29	Tai, D.-I. <i>et al.</i> , "Activation of Nuclear Factor κB in Hepatitis C Virus Infection: Implications for Pathogenesis and Hepatocarcinogenesis," <i>Hepatology</i> 31:656-664, W.B. Saunders Company (2000)		
	NPL30	Thornberry, N.A., "Caspases: key mediators of apoptosis," <i>Chem. Biol.</i> 5:R97-R103, Current Biology Ltd. (1998)		

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	NPL31	Thornberry, N.A., "The caspase family of cysteine proteases," <i>Brit. Med. Bull.</i> 53:478-490, Oxford University Press (1997)	
	NPL32	Vaishnaw, A.K. <i>et al.</i> , "The molecular basis for apoptotic defects in patients with CD95 (Fas/Apo-1) mutations," <i>J. Clin. Invest.</i> 103:355-363, The American Society for Clinical Investigation Inc. (1999)	
	NPL33	Vilner, B.J. <i>et al.</i> , "Sigma-1 and Sigma-2 Receptors Are Expressed in a Wide Variety of Human and Rodent Tumor Cell Lines," <i>Cancer Res.</i> 55:408-413, American Association for Cancer Research, Inc. (1995)	
	NPL34	Wakisaka, S. <i>et al.</i> , "Modulation by proinflammatory cytokines of Fas/Fas ligand-mediated apoptotic cell death of synovial cells in patients with rheumatoid arthritis (RA)," <i>Clin. Exp. Immunol.</i> 114:119-128, Blackwell Science Ltd. (1998)	
	NPL35	Wyllie, A.H., "Cell death: a new classification separating apoptosis from necrosis," in <i>Cell death in biology and pathology</i> , Bowen, I.D. and Lockshin, R.A., eds., Chapman and Hall, London, pp. 9-34 (1981)	
	NPL36	Wyllie, A.H. <i>et al.</i> , "Cell Death: The Significance of Apoptosis," <i>Int. Rev. Cyt.</i> 68:251-306, Academic Press, Inc. (1980)	
	NPL37	Zhou, T. <i>et al.</i> , "Bisindolylmaleimide VIII facilitates Fas-mediated apoptosis and inhibits cell-mediated autoimmune diseases," <i>Nat. Med.</i> 5:42-48, Nature America Inc. (1999)	
	NPL38	Zou, C. <i>et al.</i> , "Combined effect of chemopreventive agent N-(4-hydroxyphenyl) retinamide (4-HPR) and $\gamma$ -radiation on bladder cancer cell lines," <i>Int. J. Oncol.</i> 13:1037-1041, D. A. Spandidos (1998)	
	NPL39		
	NPL40		

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